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Thermal Spread of Vessel-Sealing Devices Evaluated in a Clinically Relevant in vitro Model

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Key Words

Vessel-sealing device • Thermal injury • Temperature spread • Nerve-sparing • Cautery

Abstract

Introduction: Bipolar vessel-sealing devices (VSDs) have advantages in urological surgeries (less hemorrhage, shorter operating time). However, these instruments can cause thermal injuries, which can result in neural damage and necrosis. The objectives of this study were to establish a reproducible in vitro model for standardized assessment of electrosurgical devices and to evaluate whether optimized placement of surgical instruments can reduce the thermal spread. **Methods:** We evaluated thermal spread of two VSDs in vitro using thin bovine muscle strips. Thermal injury was measured using an infrared camera, temperature probes and histology. The recordings were made with the VSD alone and with a rectangular clamp next to the VSD. **Results:** Both instruments showed a significant temperature spread of 2.5 mm lateral to the VSD. The placement of a metal clamp next to the VSD significantly reduced the temperature spread. Histological examinations were able to underline these findings. **Conclusions:** In this study we describe a straightforward clinically relevant in vitro model for the evaluation of future electrosurgical instruments. We demonstrated that

the thermal spread of VSD could be further reduced by optimized placement of an additional surgical instrument. Our results could help surgeons protect sensitive structures like nerves in the vicinity of the VSD.

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Introduction

Heat-mediated hemostasis has a long tradition in medicine. As early as 3000 BC, boiled oil and tools heated in a fire were applied on bleeding injuries [1, 2]. In the early 19th century, the French physicist Becquerel became the first to use electrocautery when he applied direct electric current to bleeding tissue, causing hemostasis [3]. In the late 19th century, D'Arsonval, a French biophysicist, found that the use of high-frequency alternating electric current during electrocautery could prevent painful electrical shocks [3, 4]. In 1926, Dr. Harvey Cushing and Dr. William T. Bovie introduced the first electrocautery instruments with the ability to both cut and coagulate [5, 6]. After that discovery, diathermy de-

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vices became widely used, particularly in minimally invasive procedures [3, 7].

Adequate blood coagulation during surgery is critical to a successful outcome. Good visibility in the surgical field is key for proper dissection and minimal blood loss is essential to reduce perioperative morbidity. Conventional ligation is time consuming and technically demanding, especially in the minimally invasive setting. Clips and staplers are not cost-effective, have limited security, and can only be used for small tissue strips. Therefore, bipolar electrocoagulation and vessel-sealing devices (VSDs) offer some advantages, including ease of handling and fast hemostasis that does not require the use of foreign bodies that must remain in the surgical site. However, lateral temperature spread is a major concern with the use of these devices. Tissue coagulation occurs when the temperature rises above 45°C [8–11]. If the temperature rises higher than this, cells begin to die and denaturation of proteins occurs at temperatures from 57 to 65°C [9].

Therefore, the extent of lateral thermal spread should be minimized, especially in operations where nerve-sparing is a crucial part of the procedure [12, 13]. Some studies have shown that the use of bipolar cautery devices in nerve-sparing radical prostatectomy (nsRPE) is followed by a higher rate of erectile dysfunction [8, 14, 15]. Further, bowel injuries can occur and go unrecognized for many days [16, 17]. However, lower blood transfusion rates for nsRPE were reported when modern VSDs were used [18].

In the last 10 years there has been an enormous effort to develop novel electrosurgical devices. The newest generation, the VSDs, use more sophisticated electric generators that employ active feedback to optimize power output and high compressive pressure during the sealing process. By sensing tissue impedance between two bipolar electrodes the start or stop of the bipolar radiofrequency energy that needs to be delivered is calculated by the instrument and the energy controlled with the goal to reduce thermal lateral tissue damage. Shorter operations and decreased blood loss compared to conventional ligation are the major advantages of using VSD [19]. However, worries about collateral damage by thermal injury, especially for critical structures such as nerves, still remain.

Many of the numerous electrosurgical devices on the market still await detailed investigation to determine the extent of the thermal spread resulting from their use and their potential for tissue damage. These investigations are crucial as the data they will generate will allow the sur-

geon to choose the right electrosurgical instrument for the particular surgery to be performed. In this study we described an *in vitro* model to evaluate the thermal spread and sought for strategies to further lower the thermal damage in the surrounding tissue. Using this novel model we were able to precisely describe the extent of thermal damage resulting from two different VSDs for open surgery and demonstrate how the optimal placement of a second surgical instrument can protect the tissue in vicinity.

Materials and Methods

In vitro Model

In order to precisely evaluate thermal spread, we developed a standardized *in vitro* model. Thin strips of fresh bovine muscle fascia with a mean diameter of 4 mm and a length of 6 cm were dissected longitudinally. Samples were kept at 8°C until use. The strips were hung between two parallel wires that were 6 cm apart. The strips were held in place by a vessel clamp on each side. To assure consistent traction, each clamp was pulled by a 25-gram weight that was connected to the clamp with a fine thread (fig. 1a). Prior to establishing our *in vitro* model, we analyzed infrared images taken during open radical prostatectomies. The temperature in the pelvis during surgery was $30 \pm 1.5^\circ\text{C}$; therefore, we used 30°C as the starting temperature for the muscle/fascia strips. During measurement, the strip constructs were positioned on top of a warm water bath.

In these experiments, two different VSDs were used. The first device represents the latest generation of VSDs (LigaSure Impact™ instrument 36 mm with the force triad energy platform (Valleylab, USA) and a novel proprietary sensing technology). The second device used was the LigaSure AXS™ instrument with the LigaSure-HF energy platform (Valleylab, USA). The main difference between the two devices is that the energy application during the sealing process is continuously being changed in the Impact device, whereas the older AXS instrument applies a steady energy during the whole process.

Further, we investigated the hypothesis that a metal instrument placed close by could serve as a heat sink and potentially reduce the tissue damage. We therefore placed a dissecting clamp in the open and closed position next to the VSD and recorded the effect on the thermal spread. In the open position one branch of the clamp was placed on each side of the VSD (fig. 1). Between experiments, the clamp was allowed to cool down to room temperature.

Deep Tissue Temperature Measurement

For continuous measurement of the temperature within the tissue, we used a sensor (0.4 mm diameter) with a resolution of 0.1°C (Data-Logger Thermometer 306; Voltcraft, Germany). Every second, the temperature was recorded by a personal computer (ThermoLog® Software; Voltcraft Germany) and this data was later exported to a Microsoft Excel file. The sensors were placed at 1, 2 and 3 mm lateral to the VSD. Each series of temperature measurements began with the initiation of the tissue-sealing pro-

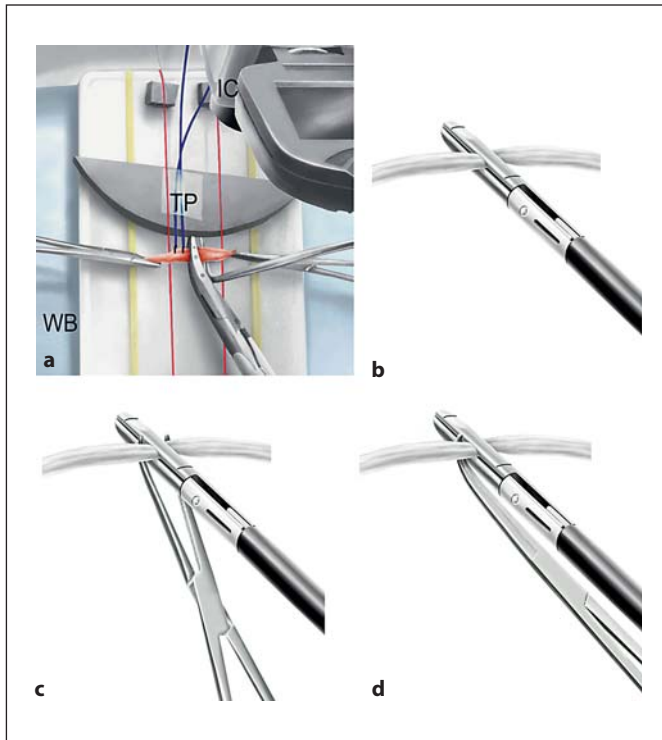


Fig. 1. Experimental setup. **a** A thin bovine muscle strip was placed on top of two perpendicular wires, laterally held by two clamps under constant tension. The strip was kept at a temperature of 30°C in a water bath (WB). The muscle strip was coagulated with the VSD. The temperature was measured by infrared camera (IC) and temperature probe (TP). **b** VSD only. **c** One branch of the rectangular clamp placed on each side of the VSD. **d** Rectangular clamp placed on one side of the sealing device.

cedure and ended when the lateral tissue temperature reached 30°C. In addition, we evaluated the maximum temperature in between the branches of each clamp, the lateral temperature velocity (time to peak temperature in seconds per distance in millimeters), the duration of temperatures over 45°C and the influence of repetitive application at the same location.

Tissue Surface Temperature Measurement

To assess the lateral temperature spread, an infrared camera (Infrared Camera IC 080; Trotec, Germany) with a resolution of 0.1°C (spatial resolution of 166 µm/pix) was mounted 20 cm above the tissue sample. The still image containing the temperature information was taken after successful termination of the sealing procedure as indicated by the sound signal from the instrument. Preliminary results did not indicate any further rise in temperature after the sealing device stopped delivering energy. Every experiment was repeated 6 times and analyzed using the program provided with the camera (SATreport®; Trotec, Germany). On both sides of the sealing instrument, an orthogonal line (region of interest) was drawn at the site of maximal temperature spread. The individual data points were transferred into Excel.

The average temperature was calculated for every experiment and a temperature curve was drawn.

Histomorphological Analysis

After the sealing process, tissue samples were collected and placed in 10% formalin solution (Accustain formalin solution 10%, neutral buffered; Sigma-Aldrich). The samples that had been heated with both branches of the surgical clip on one side of the VSD were also marked with sutures on the clip side. After 12 h, the samples were rinsed 3 times with PBS (PBS pH 7.2, 1×; Gibco, Invitrogen) and processed for histology. Sections were cut (5 µm) and stained with hematoxylin and eosin (HE). Using these slides, areas of damaged or necrotic tissue were morphometrically assessed and compared using light microscopy (Leica DM 4000 B; Leica Software). The shrinkage of tissue during processing was compensated by calculation of a coefficient. This factor was calculated by the measurement of imprints of clamp width before the fixation in formalin and after histological processing.

We measured the distance from the edge of the VSD imprints, which were easily detectable as indentations in the tissue, to the area where the muscle tissue appeared normal in terms of cell volume, striation and intact nuclei. Heat-damaged tissue contained denatured cells with loss of striation, large vacuoles, disrupted muscle fibers and shrunken nuclei.

Statistical Analysis

All presented data are expressed as the mean ± SEM. All statistical analyses were performed using SPSS v16 (SPSS Inc., Chicago, Ill., USA). When comparing data between the two sealing devices, independent t tests were used. Analysis of the differences between the three different groups (no clip, one branch on each side and closed clamp on one side) were analyzed using one-way analysis of variance. The groups were further analyzed using Bonferroni post-hoc testing if the F statistics were significant. A p value of <0.05 was considered significant.

Results

Deep Tissue Temperature Measurement

The maximal temperature in between the branches of the AXS instrument was 77.2°C (±6.3). At 1 mm lateral to the device, the deep tissue temperature measurement showed an average temperature of 47.5°C (±7.5). This temperature is still able to irreversibly damage nerve cells. However, the temperature sensor placed 2 mm laterally revealed a mean maximal temperature of 41.2°C (±4.2). When the newer Impact instrument was used, a temperature of 87.3°C (±5.4) was measured in between the branches, indicating that this instrument produces a higher maximal temperature than the AXS instrument (p = 0.215). In addition, at 1 mm lateral to the Impact device, the average temperature was measured to be 57.9°C (±5.1), indicating that the thermal spread resulting from the use of the Impact sealing device was significantly

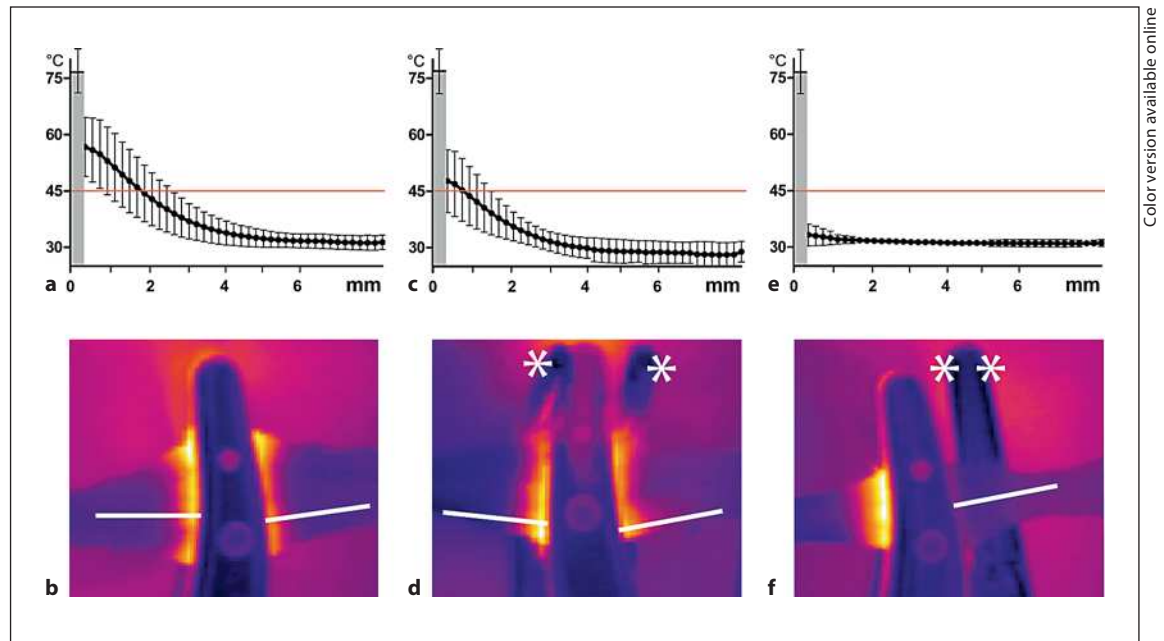


Fig. 2. Spatial temperature measurement LigaSure AXS: infrared camera measurement of the LigaSure AXS instrument. **a–f** Representative images: VSD only (**a, b**), one branch of the rectangular clamp (*) placed on either side of the VSD (**c, d**), and closed rectangular clamp (**) placed on one side of the VSD (**e, f**). Tempera-

ture values are presented in °C and distance is presented in mm. The orange line represents 45°C, the critical temperature for nerve damage. The vertical gray bar represents the average temperature between branches of the clamp.

higher ($p = 0.020$). However, the deep tissue temperature measurements revealed that despite the increased heating at the site of the Impact device, the tissue temperature at 2 mm from the device dropped to the same level as that seen with the AXS device ($41.9^{\circ}\text{C} (\pm 4.1)$; $p = 0.759$). Measurements taken at 3 mm lateral to the devices indicated that the temperature dropped to $36.9^{\circ}\text{C} (\pm 1.1)$ for the AXS instrument and $37.6^{\circ}\text{C} (\pm 1.6)$ for the Impact instrument ($p = 0.508$). The mean velocity of the temperature peak was $0.25 \text{ mm/s} (\pm 0.08)$ for both instruments.

Because the critical temperature for neural damage is 45°C , we also determined how long the temperature remained at or above this value at various distances from the sealing devices. At a distance of 1 mm the temperature remained over 45°C for an average 8.3 s (range 0–24 s) with the AXS instrument and 26.6 s (range 18–40 s) for the Impact instrument. If the sealing instrument was applied twice at the same location on the tissue strip, the temperature at 2 mm away from the instrument remained above the critical temperature of 45°C in 50% of the cases (average for the AXS: $43.0^{\circ}\text{C} (\pm 7.5)$; average for the Impact: $44.5^{\circ}\text{C} (\pm 7.2)$). As expected, if the application was repeated 3–4 times, the mean temperature also rose above the significant temperature of 45°C (three repeti-

tions: AXS: $47.2^{\circ}\text{C} (\pm 6.3)$; Impact: $47.0^{\circ}\text{C} (\pm 7.5)$; and four repetitions: AXS: $49.8^{\circ}\text{C} (\pm 5.9)$; Impact: $50.3^{\circ}\text{C} (\pm 6.1)$).

There was no significant difference between the two instruments in this experiment ($p = 0.23$).

Surface Temperature Distribution

To clearly define the spatial temperature distribution resulting from application of the VSDs, we used an infrared camera to image muscle strips during and after sealing. When the AXS instrument was applied (fig. 2) to the muscle fascia strip, infrared imaging revealed that the temperature dropped below the 45°C mark at about 1.7 mm away from the sealed site ($44.3^{\circ}\text{C} (\pm 7.5)$). In contrast, when the Impact device was used, the average spread of temperatures above 45°C reached 2.7 mm ($44.5^{\circ}\text{C} (\pm 8.7)$; fig. 3).

We hypothesized that metal surgical clamps could be used as a heat sink if placed next to a cautery device, and that this would help to protect the adjacent tissue from thermal injury during sealing with a VSD. In order to test this hypothesis, we repeated the imaging experiments using surgical clamps placed in various positions around each VSD during sealing. First, an opened right angular

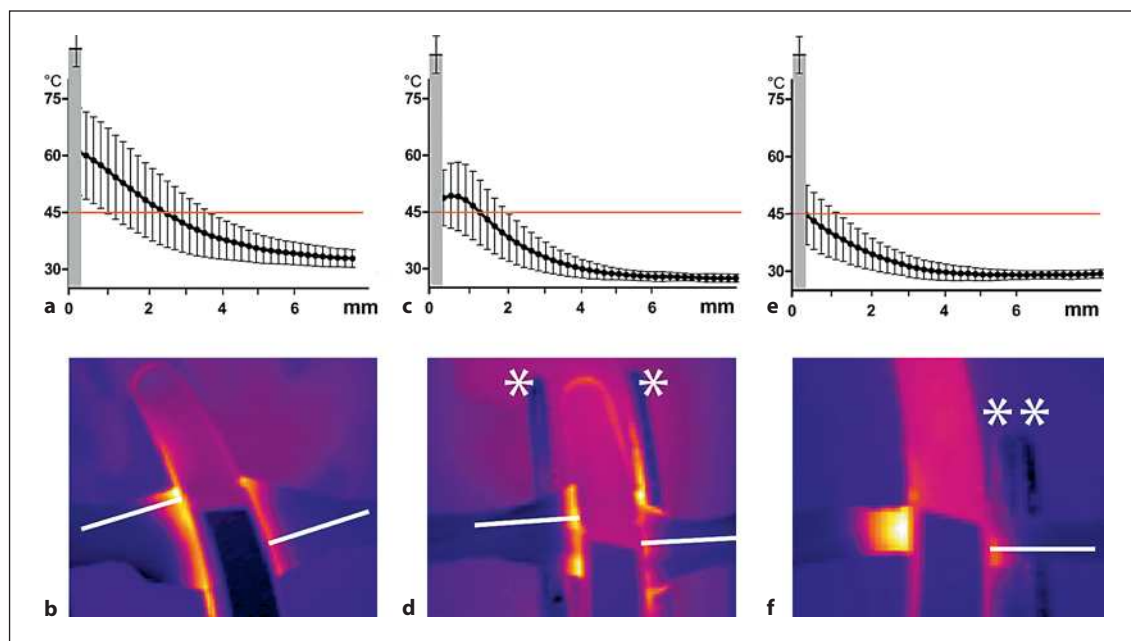


Fig. 3. Spatial temperature measurement LigaSure Impact: infrared camera measurement of the LigaSure Impact instrument. **a–f** Representative images: VSD only (**a, b**), one branch of the rectangular clamp (*) placed on either side of the VSD (**c, d**), and closed rectangular clamp (**) placed on one side of the VSD (**e, f**).

Temperature values are presented in °C and distance is presented in mm. The orange line represents 45°C, the critical temperature for nerve damage. The vertical gray bar represents the average temperature between branches of the clamp.

clamp was placed with each of its branches on either side of the AXS-sealing device. In this setting, the significant temperature spread was <0.9 mm (43.7°C (± 7.8)) laterally. Due to the small mass of the clamp branches on each side, the temperature spread was reduced but temperature rises above 45°C could not be prevented completely. However, if a closed right angular clamp was placed on one side of the VSD, infrared imaging indicated that the tissue temperature did not rise above 45°C at any point. The differences between these groups were statistically significant ($p = 0.002$). The reduction of thermal spread due to placement of the closed clamp was observed only on the side of the clamp placement. The distance of thermal spread on the contralateral side remained unchanged.

Repetition of these experiments using the Impact instrument (fig. 3) revealed the following results. The tissue temperature dropped below 45°C at about 1.2 mm (44.8°C (± 8.5)) lateral of the clamp if the clamp was placed with one branch on each side of the sealing device. In contrast, when the rectangular clamp was positioned on one side of the device, the lateral thermal spread was reduced to 0.3 mm (44.7°C (± 7.7)). The differences between these groups were statistically significant ($p = 0.001$).

Histomorphological Analysis

No carbonization of the tissue was visible in any of the muscle fascia tissue samples when they were examined macroscopically as well as microscopically (fig. 4). After heating with the AXS device, coagulation of the tissue could be seen up to 0.9 mm (± 0.10) away from the device (fig. 4b). When the branches of a surgical clamp were placed on each side of the AXS, normal tissue could be seen beginning at 0.7 mm (± 0.07) away from the device, whereas this distance could be further reduced to 0.6 mm (± 0.07) when the whole clamp was put on one side of the AXS. Although these results show a trend, they did not reach statistical significance ($p = 0.120$). When the Impact was used, coagulation of the tissue was visible up to a distance of 1 mm (± 0.09) (fig. 4c). An opened clamp placed on both sides of the Impact reduced this distance to 0.8 mm (± 0.10), and a closed clamp placed on one side of the instrument reduced the distance to 0.7 mm (± 0.18) ($p = 0.285$). The statistical analysis showed no significant difference between the two instruments in the same setting ($p = 0.666$ to $p = 0.715$).

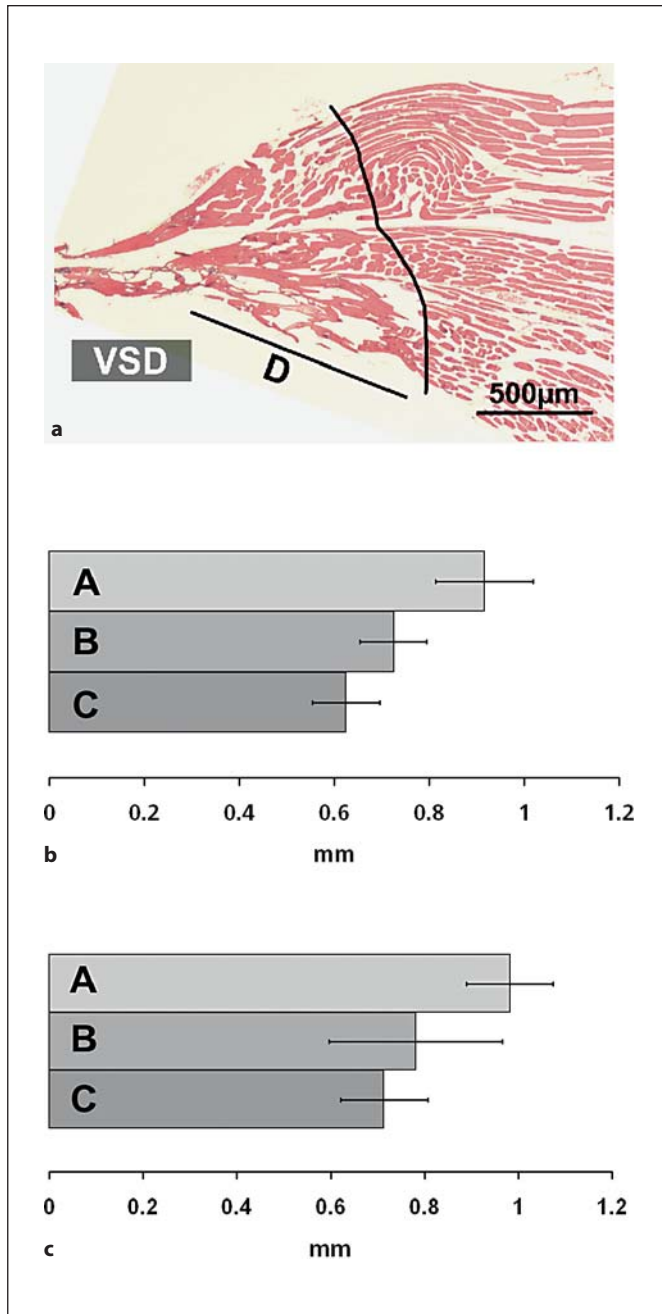


Fig. 4. Histomorphological analysis: representative HE staining of muscle-fascial tissue after application of the VSD. The distance from the edge of the sealing device to the tissue area containing morphologically normal muscle tissue was measured (a). Distance (in mm) of thermal injury as shown by histological evaluation of LigaSure AXS instrument (b) and for LigaSure Impact instrument (c). A = Without rectangular clamp (RC); B = one branch of the RC is placed on either side of the VSD; C = closed RC on one side of VSD.

Discussion

Electrosurgical devices are routinely used in many urologic procedures for open and laparoscopic surgeries. The energy delivered by these instruments raises the temperature in the tissue and induces electrocautery, or tissue sealing. However, it also causes an unintended temperature rise in proximity to the instruments, which causes collateral tissue damage. Nowadays, the surgeon can choose between many different electrosurgical instruments and many more will be induced into the market over the next years. Therefore, a reliable in vitro model is of great value to rapidly estimate the extent of the lateral temperature spread and the thermal damage to tissue, without the risks and administrative work of human or animal trials.

The focus of the experiments presented in this paper was not to evaluate the efficacy of hemostasis but to present a precise in vitro model of the thermal behavior in small tissue strips and to evaluate whether the smart placement of additional surgical instruments can protect tissue next to the bipolar device. Our results can help to make a risk assessment for various operations and enable the surgeon to decide when to use an electrosurgical or VSD. In an effort to address the issue of heat spread in a clinical situation, we recorded an open RPE procedure using an infrared camera. This preliminary experiment pinpointed limitations of the clinical approach. The angle of view and distance needed to be adjusted for every picture taken and the region of interest was often covered by instruments or the surgeon's hands. Thus, continuous temperature measurement using probes during operations would not only prolong surgery but also bears an additional risk of contamination. Further, in an actual surgery the inconsistent volume of tissue to be coagulated would introduce an unwanted high variability of the temperature readings. Nevertheless, the infrared images taken during RPE were consistent with our in vitro model.

Further support for our in vitro model is found in a recent publication by Wallwiener et al. [20]. In that study, the data acquired using an in vivo modified fallopian tube model supports our data on VSDs. Interestingly, the cooling effect of intravascular blood flow, which is discussed in studies of burn wounds, does not seem to play a significant role in the application of electrosurgical devices. This might be due to the fact that bipolar devices compress the tissue, minimizing blood flow. This also supports the use of the proposed in vitro model.

Using two independent methods of temperature measurement, we were able to define the precise lateral temperature spread of two VSDs. The temperature dropped

under the critical value for nerve damage (45°C) at a distance of 1.7 mm using the AXS instrument and 2.7 mm if the Impact instrument was used. While this distance might be sufficient in some surgical procedures, such as freeing the kidney by dissecting Gerota's fascia, clearly a steeper drop in temperature is desired for delicate procedures occurring close to neural structures (e.g. a neurovascular bundle). Therefore, we sought methods to further reduce the thermal spread. The simplest way to lower the temperature would be to add cold water. However, this would impair visibility and prolong the surgical procedure as fresh water was constantly added and removed. Interestingly, the dissecting clamp commonly used to dissect the periprostatic plane can be used as a heat sink during the sealing process. We were able to demonstrate that the placement of the dissecting clamp next to the VSD lowered the temperature spread significantly, with the largest decrease occurring when the closed clamp was placed on one side of the VSD. This measure of caution is now routinely used in our clinic if VSDs are used close to neural structures.

Histomorphometric analysis confirmed these results. Less heat damage was visible microscopically if the clamp was used as a heat sink. As expected, higher temperatures

were needed to induce structural changes that can be identified in stained tissue strips. Our data showed that increased damage occurs closer to the VSD where the tissue temperature is the greatest. Thus, this model can be used to assess different methods of VSD application. We were able to show that the common mistake of repetitive VSD application at the same location leads to a significantly greater temperature spread and more collateral tissue damage.

In conclusion, we were able to develop a straightforward in vitro model which allows rapid analysis of the thermal spread of electrosurgical devices. Further, we were able to demonstrate that the optimal placement of surgical instruments has a significant impact on the thermal spread. This strategy might be useful to protect sensitive tissues during surgery.

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